REMARKS/ARGUMENTS

By the present Amendment, claims 1, 7-12, 23-25, and 27 are pending in this application. Claims 5, 6, 14-22, 26, 28-58, 62, and 63 are canceled herein without prejudice. Claims 2-4, 13, and 59-61 were previously canceled without prejudice. Applicants reserve the right to file one or more continuation, continuation-in-part, or divisional applications towards any canceled subject matter. Claims 1, 7-12, 23-25, and 27 are amended herein to more particularly define the invention and to claim it with greater specificity. Basis for these amendments may be found throughout the specification and claims as originally filed. For example, basis for the amendments in claim 1 may be found at page 8, paragraph [0035]; page 17, paragraph [0066]; page 21, paragraph [0077]; page 22, paragraph [0078]; Examples 2-5; and Figure 1a and Figure 1b. No new matter have been added.

Claim Rejections - 35 U.S.C. §112, First Paragraph

Claims 1, 5-12, 14-58 and 62-63 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention (the written description requirement). In particular, the Action has stated that the limitation in claim 1, that "R_3 is a phosphate or phosphonate derivative of a therapeutically active agent" is allegedly not disclosed in the specification, and thus presents a new matter.

As amended herein, independent claim 1 does not recite the limitation "R_3 is a phosphate or phosphonate derivative of a therapeutically active agent." Instead, this claim recites that "the complex is 1-O-hexadecyloxypropyl-phospho-arabinofuranosyl-guanosine (HDP-P-Ara-G), 1-O-hexadecylcycloxypropyl-cyclic-cidofovir (HDP-cCDV) or hexadecyloxypropyl-3-phospho-ganciclovir (HDP-P-GCV)." This description may be found at page 8, paragraph [0035]; page 17, paragraph [0066]; page 21, paragraph

[0077]; page 22, paragraph [0078]; Examples 2-5; and Figure 1a and Figure 1b. For the same reasons, dependent claims 5-12, 14-58 and 62-63 provide sufficient written description under 35 U.S.C. §112, first paragraph. Applicants respectfully request reconsideration and removal of this rejection.

Claim Rejections - 35 U.S.C. §103(a)

Cheng I

Claims 1, 5-12, 14, 15, 22-52, and 62-63 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Cheng I (Investigative Ophthalmology & Visual Science, Feb. 2002, Vol. 43). Applicants respectfully disagree.

Applicants respectfully submit that Cheng I is not prior art to the claimed invention and therefore, is not available for rejection of the claims under 35 U.S.C. §103(a).

In support of this, Applicants first point out that Cheng I has a publication date of February 2002, which is less than one year from the priority filing date of the instant application, which claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Application No. 60/444,228, filed January 31, 2003.

Next, Applicants submit that Cheng I is not by another, but is actually the inventors own work. Applicants include with this response a declaration under 37 CFR §1.131 by inventors William R. Freeman, Lingyun Cheng, and Karl Y. Hostetler. In their Declarations, these three inventors declare that the coauthors of the Cheng I publication, namely Sunan Chaidhawangul, Michael F. Gardner, James R. Beadle, Mitsuko Toyoguchi, and Germaine Bergeron-Lynn, were students working under their direction and supervision. The inventors further declare that prior to the publication date of Cheng I, they had used the compounds disclosed in the instant application including intravitreally injectable crystalline 1-O-hexadecylpropanediol-3-phosphoganciclovir (HDP-P-GCV), for the treatment or prevention of herpes simplex virus (HSV)-1 retinitis.

Therefore, inventors William R. Freeman, Lingyun Cheng, and Karl Y. Hostetler conceived of and reduced to practice the methods claimed in the instant application before the publication date of Cheng I.

For these reasons, Applicants respectfully submit that Cheng I is not prior art to the instant claims. Applicants request reconsideration and withdrawal of this rejection.

Cheng II

Claims 1, 5-12, 14, 15, 22-52, and 62-63 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Cheng II (Investigative Ophthalmology & Visual Science, May 2000, Vol. 41, No. 6). Applicants respectfully disagree.

As amended herein, the instant claims distinguishes over Cheng II by claiming methods for treating a pathological condition of ocular tissue by contacting a therapeutically active complex with ocular tissue, wherein the complex is 1-O-hexadecyl-oxypropyl-phospho-arabinofuranosylguanosine (HDP-P-Ara-G), 1-O-hexadecylcycloxy-propyl-cyclic-cidofovir (HDP-cCDV) or hexadecyloxypropyl-3-phospho-ganciclovir (HDP-P-GCV), and wherein the pathological condition is macular degeneration, ocular proliferative or vascular diseases, and diseases of elevated intraocular pressure, thereby treating the pathological condition.

Cheng II does not teach or suggest any such methods. Instead, this publication teaches HDP-P-GCV as an intravitreal injectable drug for viral retinitis. Cheng II does not teach or suggest any methods for treating a pathological condition of ocular tissue, wherein the pathological condition is macular degeneration, ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure as required by the instant claims. The cause and treatment of viral retinitis is very different than that of macular degeneration, ocular proliferative or vascular diseases, and diseases of elevated intraocular pressure. Therefore, one of skill in the art at the time of invention, would not have been motivated or had any reason to modify the teachings of Cheng II, in order to arrive at the claimed invention.

Nor would one of ordinary skill in the art have any reasonable expectation of success in arriving at the claimed invention, either based on their own general knowledge or based on what Cheng II teaches. As described above, Cheng II teaches HDP-P-GCV as an intravitreal injectable drug for viral retinitis; whereas the claimed invention is directed to methods for treating a pathological condition of ocular tissue including macular degeneration, ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure by contacting ocular tissue with 1-O-hexadecyl-oxypropyl-phospho-arabinofuranosylguanosine (HDP-P-Ara-G), 1-O-hexadecylcycloxy-propyl-cyclic-cidofovir (HDP-cCDV) or hexadecyloxypropyl-3-phospho-ganciclovir (HDP-P-GCV). The cause and treatment of viral retinitis is very different than that of macular degeneration, ocular proliferative or vascular diseases, and diseases of elevated intraocular pressure. Therefore, one having skill in the art at the time of invention, would not have any reasonable expectation of successfully arriving at the claimed invention, by using HDP-P-GCV as taught by Cheng II, for the treatment of macular degeneration, ocular proliferative or vascular diseases, and diseases of elevated intraocular pressure.

For all these reasons, Applicants respectfully submit that the instant claims are not obvious over the teachings of Cheng II. Applicants request reconsideration and withdrawal of this rejection.

Cheng I or Cheng II in view of Unger

Claims 16-21 and 53-58 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Cheng I or Cheng II in view of Unger (U.S. Patent No. 6,120,751). Applicants respectfully disagree.

While not necessarily agreeing with the Office Action but in an effort to place this application in condition for allowance, claims 16-21 and 53-58 are canceled herein, which renders this rejection moot.

Applicants respectfully request reconsideration and withdrawal of these rejections.

CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

A Request for Continued Examination (RCE) under 37 CFR §1.114 and a petition for a three month extension of time under 37 CFR §1.136(a) accompanies this response.

The Commissioner is hereby authorized to charge a total of $960.00 as payment for the RCE fee ($405.00) and petition for the three month extension of time fee ($555.00) to Deposit Account No. 07-1896. No other fee is believed due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

Date: February 17, 2010

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